

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/020,450	MILLER ET AL.	
	<b>Examiner</b> Phyllis G. Spivack	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephone interview of December 19, 2005.
2. ☒ The allowed claim(s) is/are 1,2,4,6,9-23,33-38,42-47 and 51-72.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input checked="" type="checkbox"/> Other <u>The drawings are approved.</u></li> </ol> |
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Applicants' Amendment filed November 9, 2005 and Appeal Brief filed November 23, 2005 are acknowledged. Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 remain under consideration.

### EXAMINER'S AMENDMENT

Authorization for this Examiner's Amendment was given in a telephone interview with Lorna Tanner on December 19, 2005.

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

In claim 1, line 2, "associated with" is deleted and -- due to -- is inserted therefor.

In claim 1, line 4, -- comprising at least 80% non-alpha tocopherol -- is inserted following "composition".

The present abstract is deleted and a new abstract is inserted on a separate page.

### REASONS FOR ALLOWANCE

In the last Office Action claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 remained rejected under both 35 U.S.C. 102(e) as being anticipated by Wechter, W.J., U.S. 2004/0058987, and under 35 U.S.C. 103 as being unpatentable over Wechter, W. J., 2004/0029954. It was asserted that Wechter ('987) teaches methods for treating the symptoms of a cerebral ischemic condition in a mammalian subject comprising administering a non-alpha tocopherol enriched tocopherol composition to reduce neuronal damage related to said cerebral condition, and, respectively, Wechter ('954) broadly claims methods of treating any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which are gamma-tocopherol.

Applicants' arguments that the effective filing date of the instant application is before the effective filing dates of the '987 and '954 Wechter publications and that the specifications on which the '987 and '954 Wechter publications are based do not support the claims filed therein, are persuasive.

The rejections set forth *supra* are withdrawn.

Claims 1, 4, 9-14, 33-38, 51-63 and 67-69 were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Kobayashi et al., Free Rad. Res. It was asserted Kobayashi teaches the administration of antioxidants, such as  $\alpha$ -tocopherol and its analogs, to protect neuronal cells against cytotoxicity. In a laboratory model using HT-4 cells, a rat hippocampal cell line,  $\beta$ -tocopherol, in addition to  $\alpha$ -tocopherol, was shown to protect these cells from glutamate-induced toxicity.

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Applicants argue treatment of cerebral ischemia in a mammalian subject is not disclosed, and the concentration used in the *in vitro* model system may not be extrapolated to the *in vivo* situation.

Applicants' arguments are persuasive. The glutamate-induced cytotoxicity demonstrated by Kobayashi is a model system to study neurodegeneration due to oxidative stress, not ischemic conditions. The rejection of record under 35 U.S.C. 103 as being unpatentable over Kobayashi et al., Free Rad. Res., is withdrawn.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Cabrier de Lassauniere et al., U.S. Patent 6,297,281. It was asserted Cabrier de Lassauniere teaches the administration of two active ingredients in combination to treat cerebral ischemia. These are an NO synthase inhibitor and a trap of reactive forms of oxygen that collectively provide a highly protective effect on focal cerebral ischemia. Non-alpha tocopherols are disclosed as examples in column 4, lines 51-53.

Applicants argue Cabrier does not provide any motivation to remove the NO synthase inhibitor and use only a non-alpha tocopherol enriched tocopherol composition for treating cerebral ischemic conditions.

Applicants' argument is persuasive and the rejection of record under 35 U.S.C. 103 as being unpatentable over Cabrier de Lassauniere et al., U.S. Patent, 6,297,281, is withdrawn.

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No motivation is provided to modify the prior art and arrive at the presently claimed subject matter. Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-72 are allowed in view of the contemporary knowledge of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 23, 2005

  
Phyllis G. Spivack

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**

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### ABSTRACT

Methods for reducing neuronal damage due to a cerebral ischemic condition in a mammalian subject are disclosed comprising administering a composition having a non-alpha tocopherol enriched tocopherol composition. —.